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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,302	10/21/2005	Stanley Shepherd	2002.034US/AH06008US01	9816

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Intervet/Schering-Plough Animal Health
Patent Dept. K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
07/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,302	SHEPHERD, STANLEY	
	Examiner	Art Unit	
	SHANON A. FOLEY	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *24-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/2/06; 5/30/08; 7/9/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 5/26/09 is acknowledged. The traversal is on the ground(s) that Colin et al. do not describe an *aqueous* micellular formulation. In addition, applicant argues that Colin et al. do not disclose a formulation comprising 50-350g of water per liter of the formulation, as required by claim 1.

Applicant's traversal has been fully considered, but is not found persuasive because Colin et al. clearly teach that the veterinary formulations are aqueous, see lines 20-21 on page 2 and claims 1-6. Regarding the recitation of water, this limitation is not considered a part of the special technical feature defining the invention since it is not an ingredient in the formulation that contributes to the actual control of parasites. Even if the water were considered part of the special technical feature defining the invention, Colin et al. teach that triclabendazole is administered through pouring the formulation on the skin and the opportunity for combining this liquid formulation with other stable solutions would have been prima facie obvious to one of ordinary skill in the art, see page 6, lines 15-22. 37 CFR § 1.488 (c) states that lack of unity may evident after taking prior art into consideration that shows the invention claimed lacks novelty or is clearly obvious. The teachings of Colin et al. indicate that the special technical feature defining the instant invention does not make a contribution to the prior art. Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-29 are pending. Claims 24-29 are withdrawn due to nonelected subject matter and claims 1-23 are under consideration.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on May 2, 2006, May 30, 2008 and July 9, 2008 have been considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2 and 4-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ligon et al. (US 5,639949) and Colin et al. (WO 00/61068, previously cited).

Ligon et al. teach a formulation comprising antipathogenic substances, macrocylcic lactone, see column 4, lines 6-11, column 11, line 61 to column 12, line 22 and combining macrocyclic lactone with sulfonated benzimidazole, surfactants and solvents, such as glycols and their monomethyl or monoethyl ethers, polyethylene glycol (PEG-200), polyethylene sorbitan and water. The fatty sulfonates of Ligon et al. include sodium dodecyl sulfate. See column 17, lines 45-59 and column 18, lines 24 to column 19, line 43 and Example 58 "Liquid Formulation of Antifungal Compositions" bridging columns 77-78 and Example 59, bridging columns 78-80.

Ligon et al. do not teach that the formulation is veterinarily acceptable to control internal parasites or a first active agent as triclabendazole or that the macrocyclic lactone is ivermectin.

However, Colin et al. teach a topical "pour-on" veterinary formulation comprising triclabendazole and macrocyclic lactone, "avermectin" (which is presumably the same as the

instant "ivermectin" instantly recited) in PEG, see page 2, lines 20 to column 3, line 10, Example 1 and claims 1-6.

Since the formulation of Ligon et al. comprises a combination of a macrocyclic lactone, a benzimidazole and polyethylene glycol and the formulation of Colin et al. comprises a macrocyclic lactone, a benzimidazole and polyethylene glycol, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made that the formulation of Ligon et al. is also veterinarily acceptable. In addition, Ligon et al. specifically teach that the antipathogenic substances are used to control pathogens and disease in heterologous hosts, see column 17, lines 28-31 and that the formulation can be applied by "pouring", see column 18, lines 16-19. One of ordinary skill in the art at the time the invention was made would have been motivated to use the triclabendazole of Colin et al. in the formulation of Ligon et al. to control the infection of liver flukes, at any stage in their life cycle, see page 1, lines 7-10 of Colin et al. One of ordinary skill in the art at the time the invention was made would also have been motivated to use the ivermectin of Colin et al. in the formulation of Ligon et al. to increase the spectrum of anthelmintic organisms controlled by the instant formulation. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for combining the ingredients of Colin et al. and Ligon et al. because Ligon et al. teach the incorporation of any macrocyclic lactone, see column 3, lines 11-20 and benzimidazole, column 19, lines 3-5.

While neither Ligon et al. nor Colin et al. teach the instant range of ingredients claimed, manipulation of relative amounts of formulation components that result in differences in concentration, will not support the patentability of subject matter encompassed by the prior art,

unless there is evidence indicating that such concentration data are critical. "[W]here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The adjustment of particular conventional working conditions as well as affecting the desired therapeutic effect, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results. It would have been prima facie obvious to the artisan of ordinary skill that routine optimization of the ingredients taught by Ligon et al. and Colin et al. would have resulted in the therapeutically effective topical formulation recited in the instant claims.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ligon et al. and Colin et al. as applied to claims 1, 2 and 4-21 above, and further in view of Domb (US 7,026,290) and Egelrud et al. (US 5,981,256).

See the teachings of Ligon et al. and Colin et al. above. Neither reference teaches including polyoxyethylene (20) sorbitan monolaurate or diethylene glycol monobutyl ether in the formulation.

Domb teaches an aqueous formulation of cyclosporine class substances, including anti-parasitic agents see column 2, lines 6-18 and polyoxyethylene (20) sorbitan monolaurate as a surfactant, see column 8, lines 6-16. One of ordinary skill in the art at the time the invention was made would have been motivated to use the polyoxyethylene (20) sorbitan monolaurate of Domb in the formulation of Ligon et al. and Colin et al. because it has a high hydrophilic/lipophilic

balance to increase solubility, see column 7, lines 12-31 and column 8, lines 6-16. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for combining the polyoxyethylene (20) sorbitan monolaurate of Domb in the formulation of Ligon et al. and Colin et al. since the formulation of Domb also includes PEG 200-600, ethylene glycol and water, see column 3, lines 22-37 and Example 1 in column 10.

Egelrud et al. teach a topical formulation comprising diethylene glycol monobutyl ether as a solvent, see column 18, lines 20-30 and 45-50. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the diethylene glycol monobutyl ether of Egelrud et al. into the formulation of Ligon et al. and Colin et al. because the diethylene glycol monobutyl ether of Egelrud et al. is clearly an obvious alternative or addition to the other topical solvents known in the art, such as propylene glycols, taught by Ligon et al. and Colin et al.

While neither Domb not Egelrud et al. teach the range of ingredients instantly recited, it is maintained that differences in concentration would have been an obvious design choice to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on M-F 5:30 AM-3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
Art Unit 1619